A copy of claim to show the amendments entered is enclosed.

REMARKS

Applicant confirms the election of Group I, claim 1.

Applicant will submit certified copies of the two Indian priority documents. Applicant notes the decision of the Examiner that claim 1 is not supported in the priority document and that the application is entitled to the filing date of June 14, 2001. However, it is believed that the non-elected claims are entitled to the priority claimed. Applicant reserves the right to file divisional applications on such subject matter.

As to the claim objections, applicant has amended the claim to deal with the objection to capital letters, and the claim now ends with a period with no improper intervening periods. The last line of claim 1 (vii) now has parallel grammatical structure to the preceding recitals and has been appropriately completed. We have inserted - - about - - before "18 months" under "v" as based on line 12 of page 18 of the specification.

As to the claim rejections under 35 U.S.C. 112, the amounts under "936" have been rewritten to show that 936 microliters out of 1ml of protein were taken to do the analysis. This analysis was done at Yale University. The other terms are believed to be conventional in nature One of skill in the art would appreciate the relative amounts intended. The meaning of pro+cys has been clarified. We are still awaiting the advice as to the parentheses as regards the numbers within the Table and the Examiner is respectfully requested to give the applicant the belated opportunity to submit this information in the near future. The reference to the percent injected has been removed from the Table.

As to what data in the Table should be considered as a claim limitation, the claim is intended to set forth a specific analysis of the product and also its general properties. It is believed that a reasonable interpretation of the scope of the claim can be made on the basis of one testing a sample of the novel product. The queried terms under "g" have also been rewritten. As

regards the question as to whether the protein contains "TRP", the polypeptide K contains tryptophan. However, the amount of tryptophan could not be determined by amino acid analyzer. As indicated in the amended claim, the protein contains the total number of 160 residues.

As regards paragraph 10 of the Official Action, if the protein does contain other unidentified amino acids, applicant respectfully believes that the definition does comply with 35 U.S.C. 112 in that it defines the protein on the basis of defining certain amino acids and the properties of the protein itself so that one skilled in the art can readily determine whether a particular product does or does not fall within the scope of the claim.. Applicant, has endeavored to simplify the wording of the claim by using only "comprising" rather than both "comprising" and "including". With respect to the objection under paragraph 12 as to "partially", it is believed that one skilled in the art would realize what "soluble to some extent" means when it is stated that protein is generally water-insoluble (presumably at a neutral pH). Applicant requests that the modified language be found acceptable.

With respect to paragraph 13, the fact that the polypeptide-k is capable of sub-lingual administration is considered to be an appropriate way of describing something which on insertion into the mouth can be held sub-lingually and thus capable of passing into the individual's system in this manner.

The rejection under 35 U.S.C. 112 and the statement of the Examiner regarding the law as to whether one skilled in the art can readily determine whether a particular product does or does not fall within the scope of the claim has been carefully considered. However, applicant believes that it has significant reasons to believe that the product as identified and defined in claim 1 has not been inherently produced in the reference. The following comments are submitted for this purpose.

The cited art Jeevathayaparan et al. discloses an extract and commercially available capsules made form Momordica charantia, which had hypoglycemia activity when administered orally. The Examiner states that the said extract would comprise the protein of claim 1 of the instant application. We would like to attract the Examiner's attention to the last line of the page 23 of the cited art, wherein the authors have clearly stated that the present data from their laboratory suggest that Momordica charantia contains a non-peptide hypoglycemia agent. The statement by the authors clearly distinguishes the invention from the cited art. In addition, this

clearly establishes that the extract of the cited art does not contain the protein polypeptide K as assumed by the Examiner by stating that the extract disclosed in the cited art would contain the protein in claim 1 of the instant application. Further, the Examiner must understand that the invention of the instant application does not derive any suggestion from the cited art. Had that been the case, the inventor would have focused on the non-proteinaceous components of the extract. However, the invention clearly states that the biomolecules of the instant application claimed in claim 1 is a protein. In addition, water extract of a plant parts/fruits seeds may contain alkaloids, steroids flavouroids, phenolic, glycosides, proteins etc. Thus, to presume that hypoglycemia activity is due to protein is not right. It may be due to any of the above-stated compounds present in the mixture. All of them have to be isolated and screened against animals/human beings to identify the active component. Subsequently, its toxicity is to be tested. It took the applicant a number of years and also, hundreds of experiments to arrive at the protein of the instant application. The invention is commendable because the protein is not only an active bio-molecule but also, non-toxic, making it highly effective.

The Examiner has pointed out that seed extract of the cited art does not show significant hypoglycemia activity. However, when the protein from seeds was extracted, isolated and tested by the applicant, it showed the maximum activity. This water-insoluble protein is not only highly effective but the total amount of this protein was found to be about 14-16%, which is a very high content by all standards. This further establishes that the hypoglycemia agent of the instant application is totally distinct from the extract of the cited art. Otherwise, had the inventor derived the invention from the cited art, he would not have focused on the seed but would have gone for freeze dried fruit juice as shown in the cited art and would have easily identified the fraction biomolecules with high hypoglycemia activity.

Further, the citation showed less activity in seeds whereas applicants have shown the maximum activity. The content of water insoluble protein is 14-16% which is a very significant amount for commercial exploitation. The Examiner cannot presume the presence of protein responsible for hypoglycemia activity. Thus, isolation of a water insoluble protein with a significant efficacy with no toxicity of any kind is itself a new invention. The economic viability for human consumption is another big advantage.

Further, the presence of the polypeptide K in seeds in high percentage content indicates that it is a storage protein. In additional, the extraction process itself shows that at a particular pH, the precipitation cannot extract any compound other than protein of instant application. Also, the protein of the instant application is an acid protein and precipitates at a pH of 3, which makes it distinct from the prior art. Any water extract of a plant may show activity of a particular kind, but isolation of an active product with the sum of its properties novel should be considered a novel invention. The polypeptide-p (Khanna et al; Indian Patent no. 136565, acknowledged at page 2, line 3 of the instant application) was a partially water-soluble protein. It was a single chain unstable protein with molecular weight of approximately 11000. It is extracted by tissue culture from fruits of M. Charantia. However, the polypeptide K of the instant application has been extracted from the seeds of the plant and shows two chains. The protein is insoluble in water and shows interchangeable amino acid residues with molecular weight of the protein about 18000. The applicant has been quite focused and has very objectively conducted an experiment to identify and isolate an active and safe hypoglycemia protein.

For the above reasons, the rejections are believe to have been successfully traversed and the application is believed to be in allowable form (subject to the missing information regarding parentheses mentioned above). A notice of allowability is respectfully requested in this regard.

Respectfully submitted,

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Marked up copy showing amendments

1. A ~~novel~~ protein (polypeptide-k) extracted from Momordica charantia comprising the following amino acids ~~including~~:

Amino acid	~~aka~~ 936 microliters/ 1 ml. portion	Avg moles	µgrams	mole percent	# residues
~~C~~ysac ~~cmcys~~					
~~Asx~~ aspartic acid	3.6346	3.635	0.418	9.4%	15.0
~~T~~thr	1,1549	1.155	0.117	3.0%	4.8
~~S~~ser	2.0456	2.046	0.178	5.3%	8.5
~~G~~glx	6.6195	6.619	0.848	17.1%	27.4
~~pro-+cys~~ pro-cysteine and cystein	(2.1133)	(2.113)	(0.205)	5.5%	(8.7)
~~G~~gly	3.4509	3.451	0.197	8.9%	14.3
~~A~~ala	2.8168	2.817	0.200	7.3%	11.6
~~V~~val	2.6160	2.616	0.259	6.8%	10.8
met	0.5625	0.563	0.074	1.5%	2.3
~~Heu~~ isoleucine	1.8404	1.840	0.208	4.8%	7.6
leu	3.1701	3.170	0.359	8.2%	13.1
tyr	1.0645	1.064	0.174	2.7%	4.4
phe	1.6115	1.612	0.237	4.2%	6.7
his	(1.2110)	(1.211)	(0.166)	3.1%	(5.0)
lys					
trp	(could not be determined by amino acid analyzer)				
agr	3.5602	3.560	0.556	9.2%	14.7
~~% rejected~~	~~100%~~				
				Total number of residues	160

, ~~S~~ said polypeptide-k having the following properties:

i. being water insoluble but ~~partially~~ soluble to some extent at pH 9.5 and completely soluble in 10% formic acid,

ii. being capable of sub-lingual administration,

iii. having free N-terminal,